

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 58 pertaining to good laboratory practice for non-clinical laboratory studies have been approved under OMB control number 0910–0119. The collections of information in 21 CFR part 11 pertaining to electronic records and signatures have been approved under OMB control number 0910–0303.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: May 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–11211 Filed 5–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics Meeting

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting. This meeting is open to the public. The public is welcome to obtain the link to attend this meeting by following the instructions posted on the Committee website: <https://ncvhs.hhs.gov/meetings/full-committee-meeting-13/>.

NAME: National Committee on Vital and Health Statistics (NCVHS) Meeting

DATES: Wednesday, June 14, 2023: 10:00 a.m.–4:30 p.m. EDT.

ADDRESSES: Virtual open meeting.

FOR FURTHER INFORMATION CONTACT:

Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, or via electronic mail to vgh4@cdc.gov; or by telephone (301) 458–4715. Summaries of meetings and a roster of Committee members are available on the NCVHS website <https://ncvhs.hhs.gov/>, where further information including an agenda and instructions to access the broadcast of the meeting will be posted.

Should you require reasonable accommodation, please telephone the CDC Office of Equal Employment Opportunity at (770) 488–3210 as soon as possible.

SUPPLEMENTARY INFORMATION:

Purpose: As outlined in its Charter, the National Committee on Vital and Health Statistics assists and advises the Secretary of HHS on health data, data standards, statistics, privacy, national health information policy, and the Department's strategy to best address those issues. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA),¹ NCVHS advises the Secretary on administrative simplification standards, including those for privacy, security, adoption and implementation of transaction standards, unique identifiers, code sets, and operating rules adopted under the Patient Protection and Affordable Care Act (ACA).²

The purpose of this meeting is to provide a public forum for the Committee to consider what comments it will make on the April 17, 2023, Notice of Proposed Rulemaking (NPRM) “HIPAA Privacy Rule to Support Reproductive Health Care Privacy” which is available at <https://www.federalregister.gov/documents/2023/04/17/2023-07517/hipaa-privacy-rule-to-support-reproductive-health-care-privacy>.

In addition, the Committee will consider what recommendations it will make in response to updated and new operating rules proposed by the Council for Affordable Quality Health Care (CAQH), Committee on Operating Rules for Information Exchange (CORE), to support adopted HIPAA standards, and an updated version of the X12 standard

¹ Public Law 104–191, 110 Stat. 1936 (Aug 21, 1996), available at <https://www.congress.gov/104/plaws/publ191/PLAW-104publ191.pdf>.

² Public Law 111–148, 124 Stat. 119, available at <https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf>.

for claims and electronic remittance advice transactions (Version 8020) proposed by X12. The Committee developed these recommendations in response to formal proposals received from CAQH CORE³ and X12⁴ respectively, informed by a Request for Comment (RFC) and two-day hearing held January 18–19, 2023.⁵ Details on the recent RFC and hearings are available on the Committee's website here: <https://ncvhs.hhs.gov/meetings/standards-subcommittee-hearing/>.

The Committee will reserve time on the agenda for public comment. Meeting times and topics are subject to change. Please refer to the agenda posted on the NCVHS website for updates: <https://ncvhs.hhs.gov/meetings/full-committee-meeting-13/>.

Sharon Arnold,

Associate Deputy Assistant Secretary, Office of Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2023–11207 Filed 5–24–23; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small

³ Letter from CAQH CORE to NCVHS, May 23, 2022: <https://ncvhs.hhs.gov/wp-content/uploads/2022/09/CAQH-CORE-Board-Letter-to-NCVHS-re-New-Updated-OR-052322-508.pdf>.

⁴ Letter from X12 to NCVHS, June 7, 2022: <https://ncvhs.hhs.gov/wp-content/uploads/2022/09/X12-Request-for-review-of-8020-transactions-060822-to-NCVHS-508.pdf>.

⁵ See, Subcommittee on Standards, National Committee on Vital and Health Statistics, Hearing on Requests for New and Updated Transaction Standards and Operating Rules, available at <https://ncvhs.hhs.gov/meetings/standards-subcommittee-hearing/>.

Business: Instrumentation, Environmental, and Occupational Safety.

Date: June 15–16, 2023.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Joonil Seog, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-402-9791, joonil.seog@nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Tissue Engineering Study Section.

Date: June 20–21, 2023.

Time: 9:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jonathan Arias, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, (301) 435-2406, ariasj@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA-OD22-028: The Intersection of Sex and Gender Influences on Health and Disease.

Date: June 20–21, 2023.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Courtney M Pollack, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-594-3671, courtney.pollack@nih.gov.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Pathobiology of Kidney Disease Study Section.

Date: June 21–22, 2023.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Atul Sahai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818, Bethesda, MD 20892, 301-435-1198, sahaia@csr.nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Integrative Myocardial Physiology/ Pathophysiology A Study Section.

Date: June 21–22, 2023.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Abdelouahab Aitouche, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4222, MSC 7814, Bethesda, MD 20892, 301-435-2365, aitouchea@csr.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Reproductive, Perinatal and Pediatric Health Study Section.

Date: June 21–22, 2023.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Cynthia Chioma McOliver, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1007G, Bethesda, MD 20892, (301) 594-2081, mcolivercc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Applied Immunology and Vaccine Development.

Date: June 21–22, 2023.

Time: 10:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dayadevi Jirage, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4422, Bethesda, MD 20892, (301) 867-5309, jjiragedb@csr.nih.gov.

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; Bacterial Virulence Study Section.

Date: June 21–22, 2023.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Susan Daum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, Bethesda, MD 20892, 301-827-7233, susan.boyle-vavra@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Computational, Modeling, and Biodata Management.

Date: June 21, 2023.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marie-Jose Belanger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm 6188 MSC 7804, Bethesda, MD 20892, 301-435-1267, belangerm@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 19, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-11147 Filed 5-24-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2023-0002; Internal Agency Docket No. FEMA-B-2342]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: Comments are to be submitted on or before August 23, 2023.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location <https://hazards.fema.gov/femaportal/prelimdownload> and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are